# Lytix Biopharma AS

*Promising efficacy signal in two ongoing Phase II trials*

## Fourth quarter 2023 presentation

February 29, 2024

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# Presenting team

## Øystein Rekdal – CEO and co-founder

- Dr. Rekdal's post-doctoral research forms the basis of Lytix Biopharma's technology platform.
- Over the last years Rekdal has been instrumental in the development of intra-tumoral therapy of LTX-315 from preclinical to clinical 'proof of concept'-studies.
- He previously served Lytix in various roles including CSO, and Head of R&D.

## Graeme Currie - CDO

- Over 30 years of drug development experience in both pharmaceutical and biotechnology companies
- Has successfully led drug development programs and has held key roles in the development of 8 approved drugs.
- Dr. Currie holds a PhD from Aston University in the UK.

## Gjest Breistein – CFO

- Mr. Breistein has eight years of experience from PwC as an auditor and consultant working with public and private companies across multiple industry sectors.
- Prior to joining Lytix Biopharma, he was in PwC's capital markets group advising clients in capital market transactions, financing and listing processes.

## Robert Andtbacka – Key opinion leader

- A highly reputed key opinion leader with more than over 25 years of experience in clinical research and development in melanoma and intra-tumoral immuno-oncology
- Has led over 50 clinical studies evaluating 20 novel immune-oncology therapies including the Phase III clinical trial which led to the approval of the oncolytic virus TVEC

# Lytix is addressing a major challenge in cancer therapy

**Each tumor** has several different unique mutations making it difficult to treat

**Lytix's technology** overcomes this major challenge by generating broad tumor-specific immune responses in each patient

# Lytix Biopharma at glance

*"Dedicated to being part of tomorrow's cancer treatment*

## Company overview

- Clinical-stage, immuno-oncology company
- Listed and headquartered in Oslo
- Technology platform derived from world leading research on host defense peptides
- Encouraging interim data in two ongoing Phase II studies
- International management team with presence in both US and Europe
- US Life Science specialist as largest shareholder PBM Capital
- Licensing deal with Nasdaq-listed Verrica Pharmaceuticals

## Product candidates and portfolio

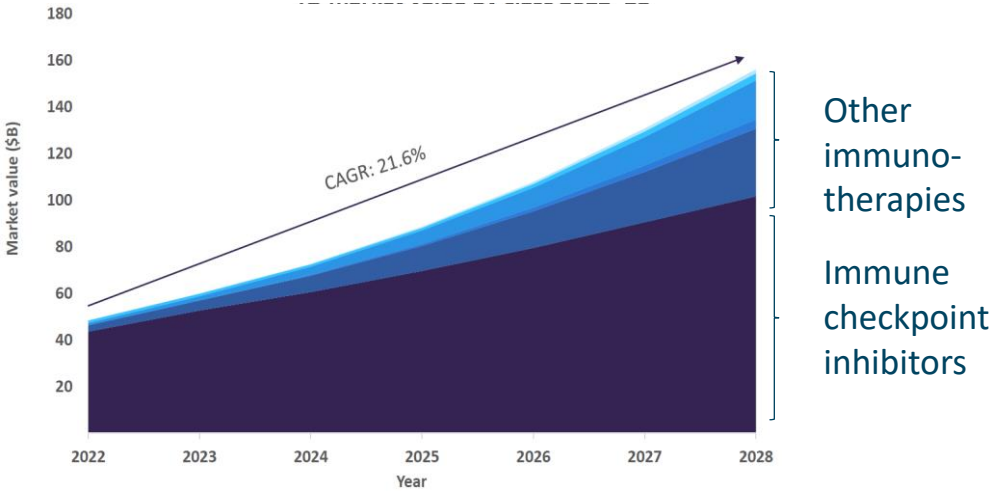
| PRODUCT | DESCRIPTION | INDICATION | PROGRESS | RESULTS EXPECTED |
|---|---|---|---|---|
| LTX-315 | Atlas-IT-05 Pembrolizumab (Keytruda®) | Melanoma (mole) patients progressed on checkpoint inhibitors | Phase II | 2025 |
| | Phase II by Verrica Pharmaceuticals (monotherapy) | Basal cell Carcinoma (skin cancer) | Phase II | Mid 2024 |
| | NeoLIPA Neoadjuvant therapy | Early.stage melanoma | Phase II | H1 2025 (interim) |
| LTX-401 | Phase I Monotherapy | Deep seated cancer | Preclinical | 2025 |

# High revenue potential for Lytix molecules

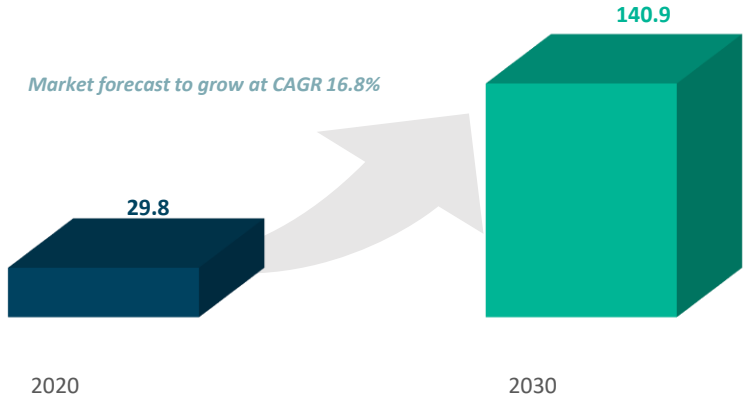
## *- monotherapy and in combination therapies*
## *- multiple cancer indications*

- The global market value for cancer immunotherapies has increased sharply over the past 10 years
- This growth is driven by immune checkpoint inhibitors (ICIs)
- Therapies that address the shortcomings of ICIs are highly needed
- By addressing the challenge for patients who do not respond to ICIs Lytix molecules represent a large commercial potential
- Other therapy methods than ICIs expected to grow at a significant pace going forward. Estimated to amount to a total of ~USD160bn within 2028 (both ICI and other immunotherapies).

**INCREASING GROWTH PROSPECTS FOR OTHER IMMUNOTHERAPIES**




**GLOBAL IMMUNE CHECKPOINT INHIBITORS MARKET (USDbn)**




*Source: GlobalData, Pharma Intelligence Center*

Source: Research and Markets. www.researchandmarkets.com/reports5561182

# Highlights for the fourth quarter

*- and post-period events*

- **Verrica Pharmaceuticals' Phase II study in basal cell carcinoma – Positive early results**
  - Verrica presented positive early results in August 2023.
  - In January 2024, Verrica reported that all patients have been dosed with LTX-315.
    - This is a significant milestone in Verrica's commitment to complete the entire study in H1 2024.
- **ATLAS-IT-05 study ongoing – Encouraging interim data from 20 melanoma patients**
  - Disease control in approximately half the patients and with durable responses for up to one year
  - One patient achieving a partial response.
  - Evidence of tumor shrinkage in both injected and non-injected lesions.
  - LTX-315 in combination with pembrolizumab was well tolerated.
- **Expanding to earlier stage melanoma patients with a stronger immune system**
  - An investigator led Phase II study at Oslo University Hospital, Radiumhospitalet planned to start H1 2024.
  - The study protocol was presented at the 15th Nordic Melanoma Meeting in October 2023.
  - In December 2023, the clinical trial application for the NeoLIPA trial was submitted to the regulatory authorities for approval.

# Highlights for the fourth quarter

*- and post-period events*

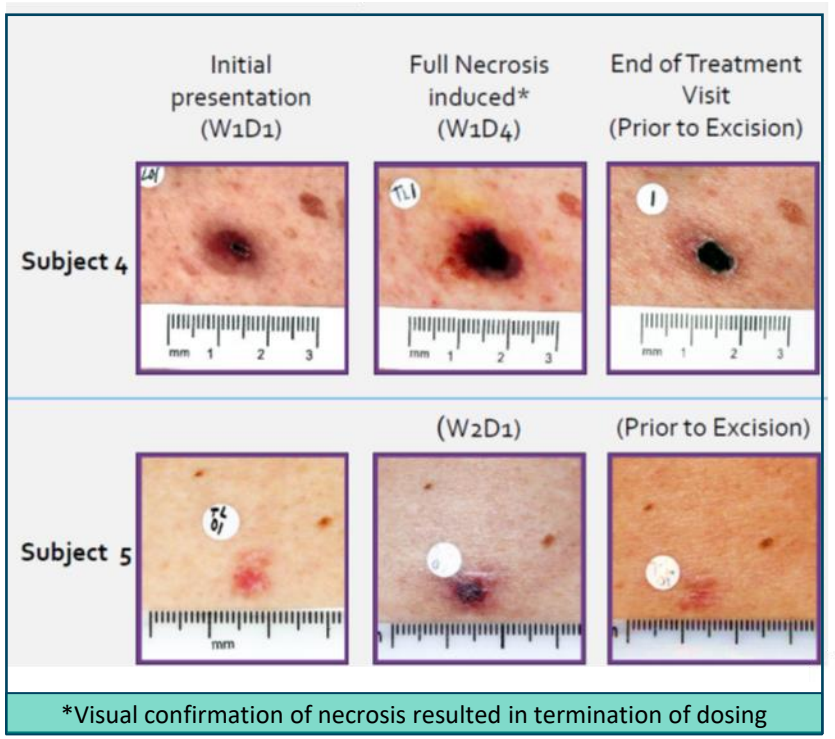
- **Clinical results published in high profiled journal**
  - A paper entitled “LTX-315 and adoptive cell therapy using tumor-infiltrating lymphocytes generate tumor specific T cells in patients with metastatic soft tissue sarcoma” published in the high-profiled, open access journal *OncoImmunology*, December 2023.
- **A paper describing LTX-315`s ability to activate specific immune cells accepted for publication.**
  - The paper describing LTX-315`s unique way of activating immune cells that are critical for T cell priming has been accepted for publication in the high profiled journal *Frontiers in Immunology*.
- **Strengthening Intellectual Property**
  - Two Patent Corporation Treaty (PCT) applications were filed December 2023 to secure additional IP protection.
- **Financial support granted from Norwegian Research Council**
  - In October, the Research Council of Norway approved Lytix’s application for up to NOK 14.3m of non-dilutive financial support from the ‘SkatteFUNN’ R&D tax incentive scheme for a project in respect of its lead program: ‘Intratumoral LTX-315 in advanced melanoma’.

# Clinical/Operational update

# Encouraging early results from Phase II study in basal cell carcinoma

- Part 1
  - Of the 6 patients treated with LTX-315 (VP-315) at the highest dose, complete histological clearance was observed in 4 injected lesions, 95% and 30% clearance in two other injected lesions
- Enrollment completed January 2024
- Phase II study results expected mid 2024

LTX-315 represents a non-surgical alternative for patients suffering from BCC




*Visual confirmation of necrosis resulted in termination of dosing

BCC market expected to increase from 6.7 billion USD in 2021 to 11.4 billion USD by 2028 Lytix entitled to receive regulatory and sales milestones at >100 mill. USD, and royalty rates from low double-digits to mid-teens

*Source: Dr. Neal Bhatia; AAD INNOVATION ACADEMY 2023, August 10-13th, Tampa Florida*

# ATLAS-IT-05: Enrollment of 20 patients completed

- Recruitment of **20** patients completed August 2023
- Late-stage melanoma patients that have previously failed to respond to PD-(L)1 inhibitor therapy
- Enrolled patients had failed ≤3 prior lines of treatment, including dual checkpoint inhibition or BRAF/MEK inhibition or oncolytic virus
- Encouraging preliminary interim data from **14** patients presented at ESMO, Oct 23rd:
- Majority of patients (62%) had Stage IV disease with a poor prognosis

**US sites**

- The University of Texas MD Anderson Cancer Center
- UPMC Life Changing Medicine
- Levine Cancer Institute
- Mount Sinai

**European sites**

- Gustave Roussy Cancer Campus Grand Paris
- HCL Hospices Civils de Lyon
- Cima Universidad de Navarra
- Oslo University Hospital Norwegian Radium Hospital
- CHU Lille
- Akershus Universitetssykehus

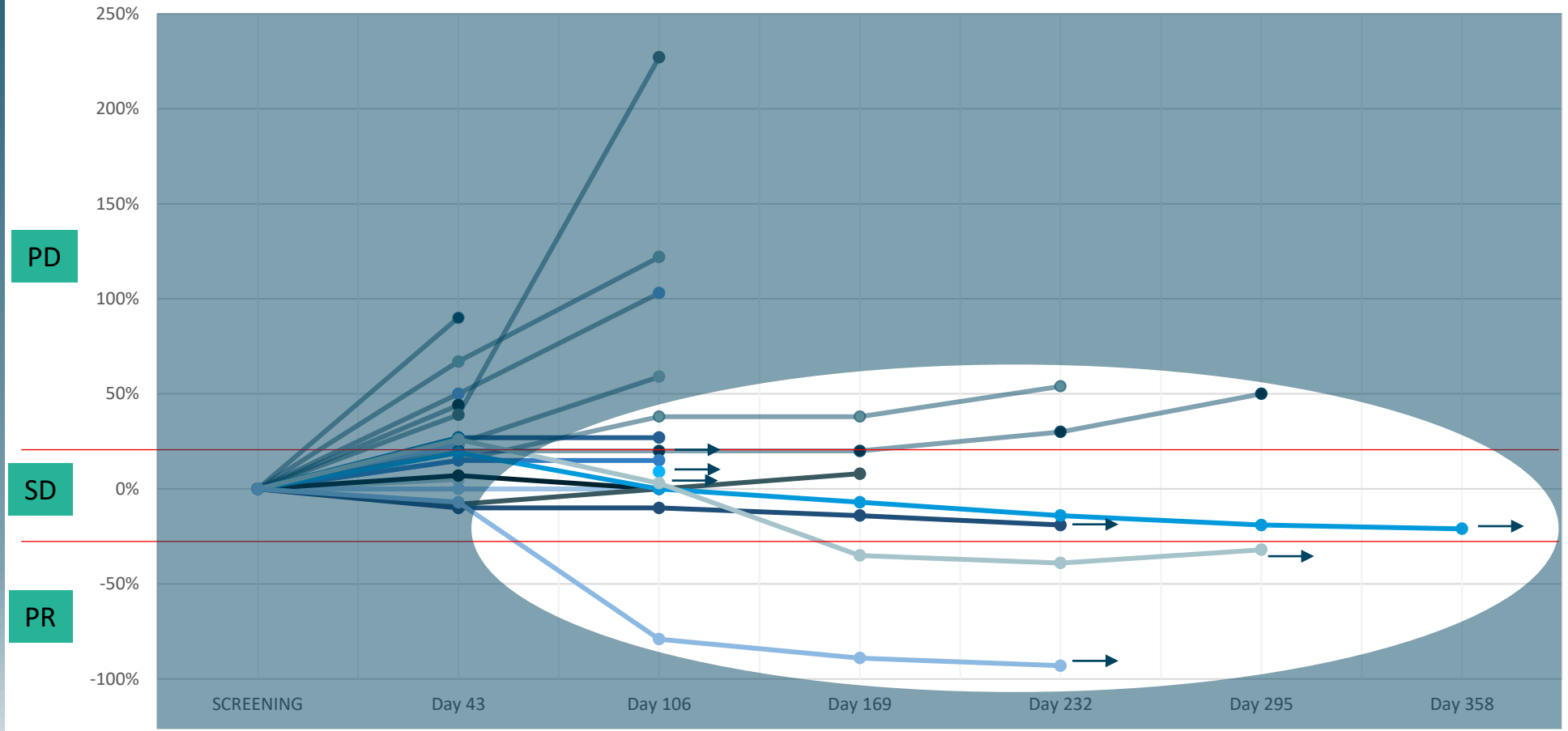
# Promising results in a challenging patient population
## - Disease stabilization in approximately half of the patients

- Interim data from all patients have been collected and analyzed
  - Durable responses with stable disease up to one year
  - One partial response so far
  - Patients with progressive cancer have larger tumor burden than patients with stable disease
- Some patients still early in the study

| Best overall response | n (%) |
|---|---|
| Partial Response | 1 (5%) |
| Stable Disease | 8 (40%) |
| Progressive Disease | 11 (55%) |

# Several patients with prolonged clinically relevant response

*- Some patients still in early stage of the study*



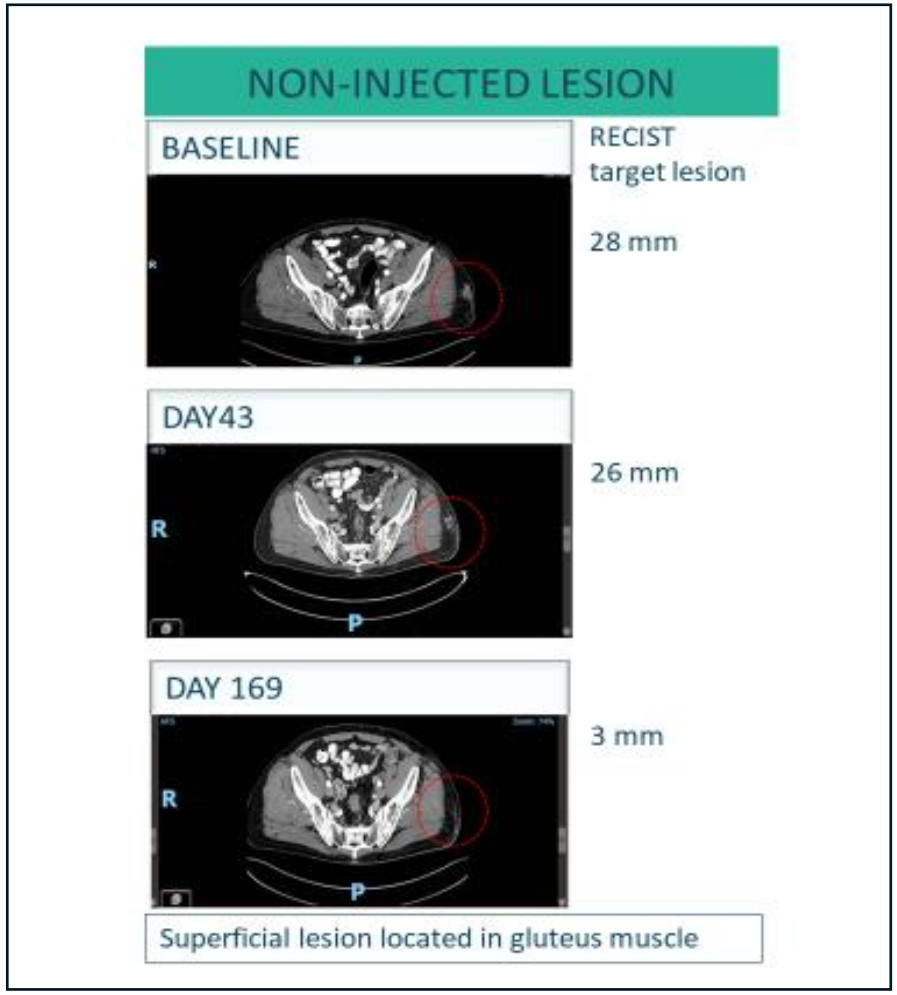

Each line in the figure represent one patient

PD: progressive disease, SD: stable disease, PR: partial response, CR; complete response

# Evidence of effects in non-injected lesions

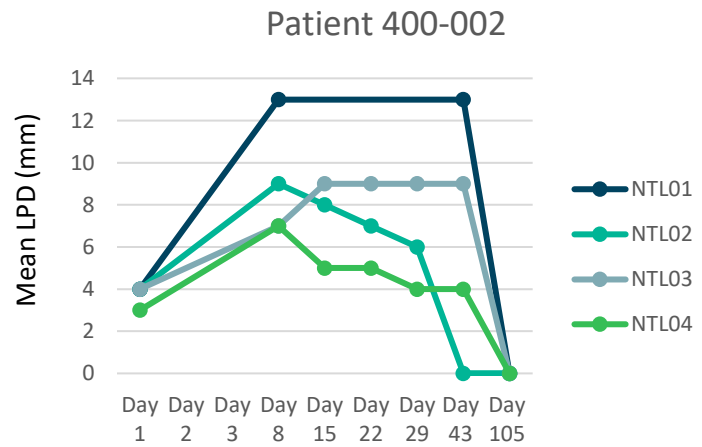
- A number of patients showed shrinkage of non-injected lesions
  - Shrinkage ranging from 93% to 9%

- Case study
  - 75-year-old male with Stage IVm1a melanoma (BRAF positive)
  - Multiple metastases in lymph nodes and gluteal muscle
  - Prior treatment: nivolumab (anti-PD-1) and BRAF/MEK inhibitor
  - Complete regression of all 4 injected lesions
  - Durable partial response with non-injected lesion shrinkage of -93%



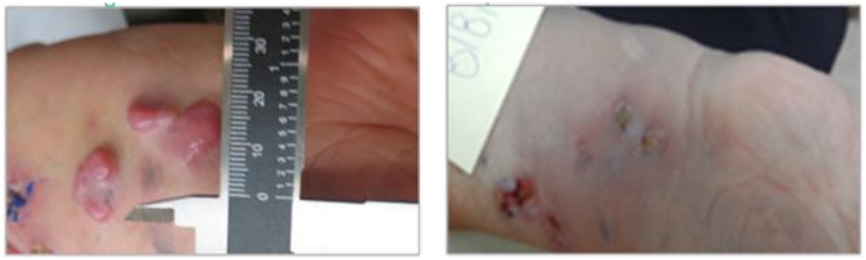
# Responses in injected lesions

- Complete regression obtained in a number of injected lesions
- Injected lesions with complete regression ranging between 3-15 mm (mean diameter)




Complete regression of all injected lesions at Day 105

Complete regression of lesions on a forearm



Before Treatment | Day 43

Complete regression of lesion behind the knee

Before treatment | Day 43

# Summary of interim results (ATLAS-IT-05)

- The combination of LTX-315 and anti-PD-1 therapy (pembrolizumab) show effects in patients that have previously failed to respond to anti-PD-(L)-1 therapy
- Enrolled patients had generally poor prognostic factors and some patients had also failed on dual checkpoint inhibition (ipi + nivo), BRAF/MEK inhibition or oncolytic virus
- Efficacy signal is encouraging with a stabilization of disease in approximately half of the patients and 1 patient achieving a partial response to date
- Evidence of tumor shrinkage in both injected and in non-injected lesions
- The trial is still ongoing and further details will be shared in a future presentation

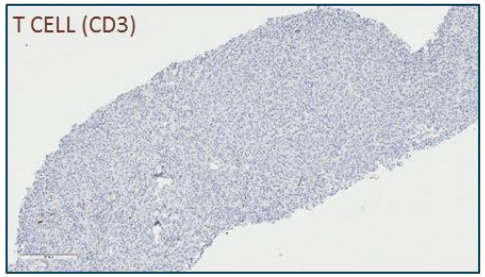
# LTX-315`s strong ability to generate broad tumor specific T-cell responses makes it ideal for earlier-stage cancer

## Proof of principle from previous studies

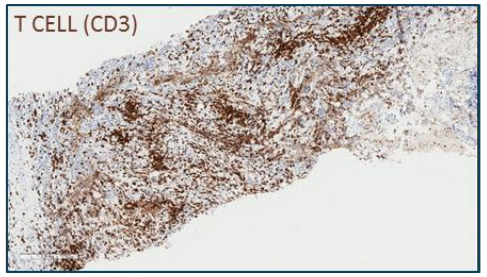
1. Infiltration of T cells in majority of treated patients
2. Expansion of up to more than 100 different T- cell clones
3. Expansion of tumor cell- and neoantigen-specific T-cell clones

## 1. High number of T cells

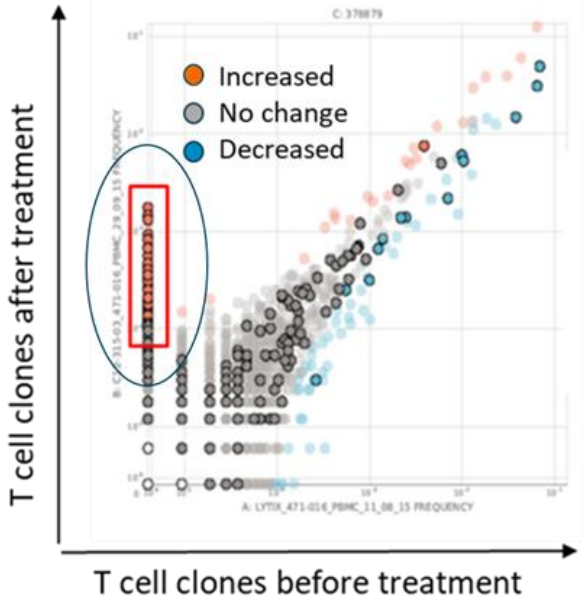
Before treatment



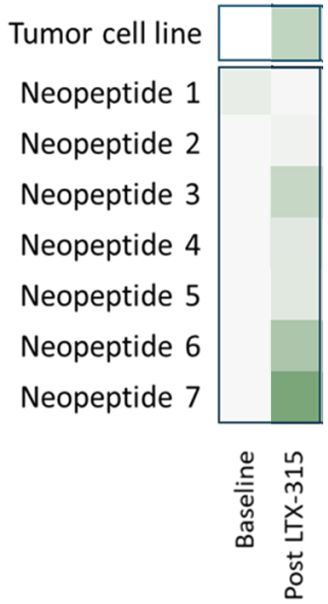

After treatment




## 2. Broad repertoire of T cells




## 3. Patient specific T cells



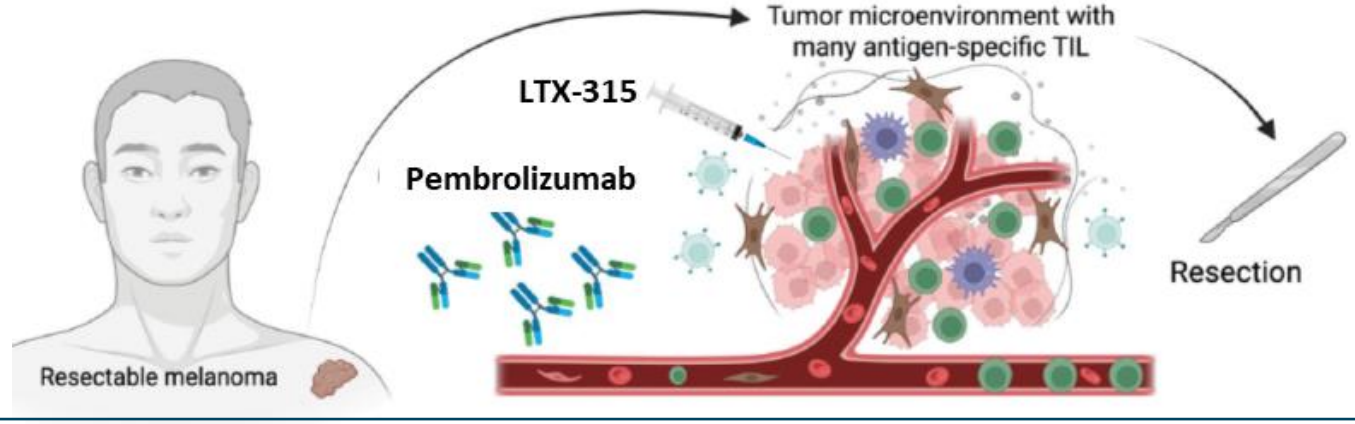

LTX-315 is likely to have even greater effectiveness in early-stage cancer patients with lower tumor burden and a more responsive and intact immune system.

# Planned neoadjuvant study with LTX-315 in earlier stage melanoma patients (NeoLipa)

- LTX-315 added to the currently recommended neoadjuvant treatment (immune checkpoint inhibitor, pembrolizumab) before surgery for resectable stage III/IV melanoma
- Principal investigator, dr. Henrik Jespersen, Head of melanoma oncology, Oslo University Hospital - Radiumhospitalet
- Study start: 1H 2024
- Rationale:
  - Investigate any added clinical effect of LTX-315 in earlier stage patients with a stronger immune system
  - Expected to result in more effective T-cell priming and reduce risk of relapse compared with pembrolizumab monotherapy

**Neoadjuvant therapy:** Treatment before surgery

Lytix molecules may have a potential in neoadjuvant setting in several cancer indications

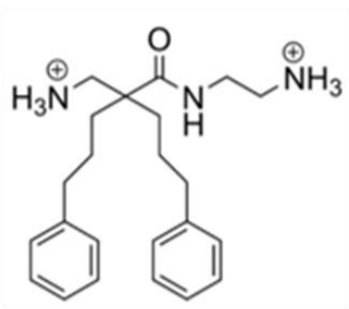




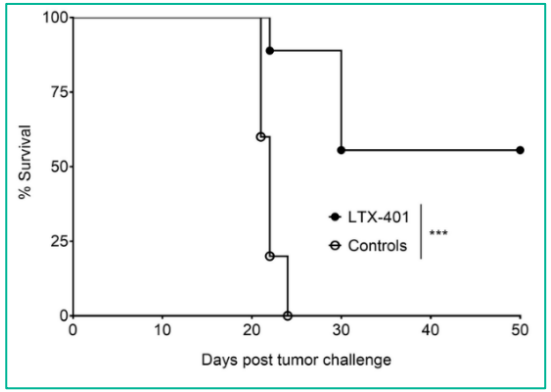

*Source: Figure adapted and modified from Saad & Tarhini, Current Oncology Reports 2023*

# LTX-401: optimized for deep-seated solid tumors

- Robust effects in several pre-clinical cancer models, including liver cancer
- Safe and well tolerated in preclinical safety studies
- Synergy with checkpoint inhibitors
- High potency (can be administered in high doses and over longer time)
- Ideal also for deep seated tumors in indications with a large commercial potential
- Being prepared for Phase 1




LTX-401




- **Small oncolytic molecule developed for intra-tumoral administration**
- **Cured 50% of the animals with liver cancer (hepatocellular carcinoma) with two doses only**

# A perspective view on ATLAS-IT-05 interim data and Lytix`s focus on earlier stage cancer

By Robert Andtbacka

# Introduction to Dr. Robert Andtbacka

- Internationally renowned surgical oncologist with more than over 25 years of experience in immuno-oncology clinical research and development and a highly reputed leader in melanoma and intratumoral immuno-oncology
- Has led over 50 clinical studies evaluating the activity of 20 novel immune-oncology therapies during Phase 1 to Phase 3 trials, including the Phase III clinical trial which led to the approval of the oncolytic virus TVEC in patients with unresectable metastatic melanoma
- Joined Huntsman Cancer Institute at the University of Utah in 2006 where he served as Director of the Melanoma Clinical Research Program and established an internationally recognized comprehensive program in intratumoral immuno-oncology
- Has served as Chief Medical Officer for Seven and Eight Biopharmaceuticals, where he led the clinical development of immunostimulatory molecules , later acquired by Eikon Therapeutics
- Is currently serving as Chief Medical Officer at HiFiBIO Therapeutics, a biotechnology company focusing on immunomodulatory antibodies.

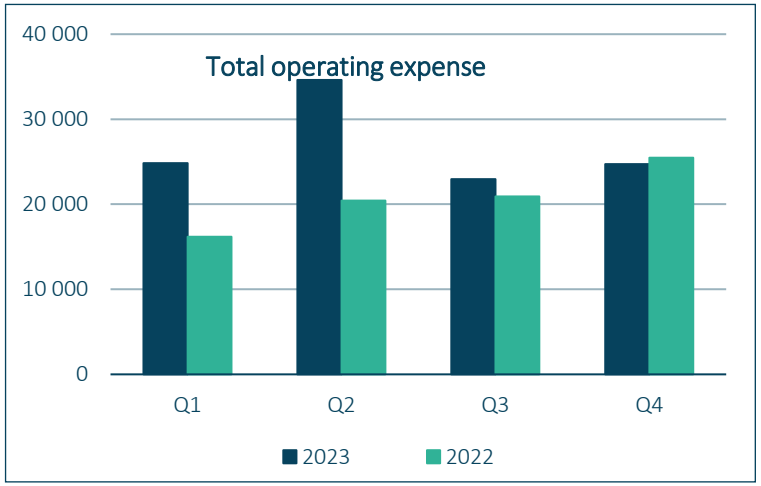
# Key figures

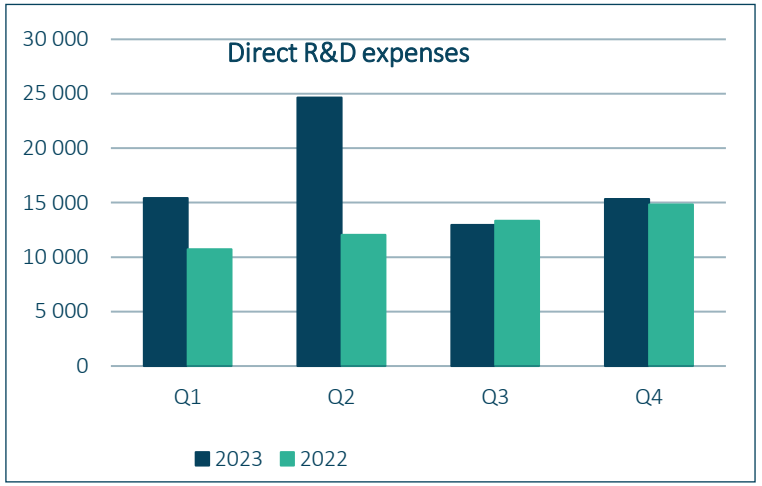
# Key figures – profit and loss

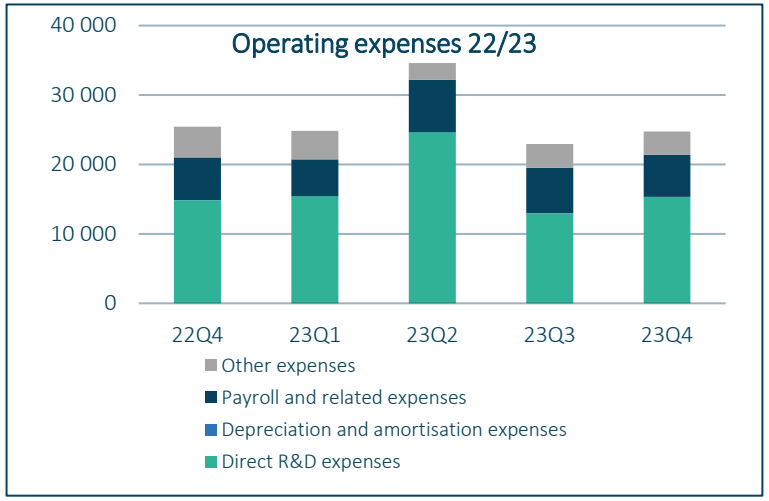
| *Amounts in NOK thousands* | *Unaudited* Q4 2023 | Q4 2022 | *Unaudited* H2 2023 | H2 2022 | *Unaudited* FY 2023 | FY 2022 |
|---|---|---|---|---|---|---|
| Total operating income | 5,125 | 1,615 | 9,417 | 4,587 | 10,241 | 17,273 |
| Total operating expenses | (24,729) | (25,453) | (47,665) | (46,368) | (107,118) | (82,968) |
| Loss from operations | (19,604) | (23,837) | (38,247) | (41,781) | (96,877) | (65,695) |
| Loss for the period | (18,580) | (29,195) | (36,828) | (40,343) | (87,937) | (56,006) |

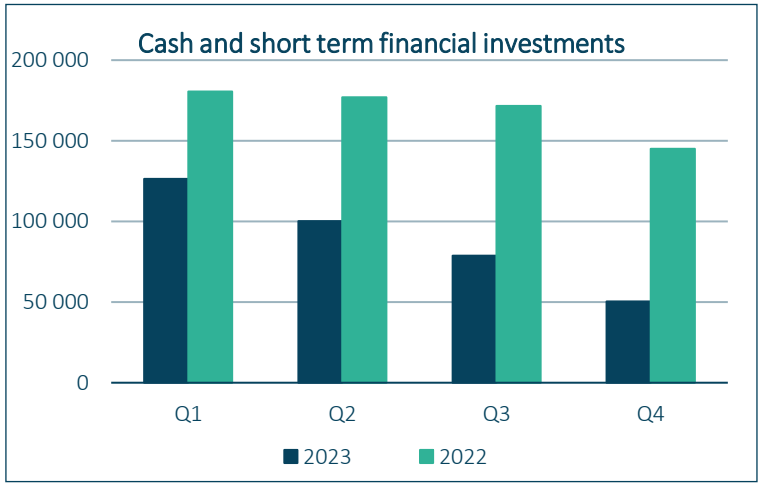
- Total operating income for the three months ended 31 December 2023 was NOK 5,125 million and is related to governmental grants, compared to NOK 1.6 million for the same period in 2022. In Q4 Lytix's application for SkatteFunn was approved resulting in a grant of NOK 4.8 million recognized as income in this period.
- Total operating expenses for the three months ended 31 December 2023 amounted to NOK 24.7 million compared to NOK 25.5 million for the same period in 2022
  - The major cost driver for the quarter is the ATLAS-IT-05 trial in the US and EU. The study is fully recruited, and patients are continuing on the trial.

# Strict cost discipline while prioritizing clinical activities



# Key figures – balance sheet

| *Amounts in NOK thousands* | *Unaudited* 31.12.2023 | 31.12.2022 |
|---|---|---|
| **Assets** | | |
| Property, plant and equipment | 110 | 124 |
| Trade and other receivables | 12,777 | 6,735 |
| Short-term financial investments | 23,183 | 50,606 |
| Cash and cash equivalents | 27,365 | 94,552 |
| **Total assets** | 63,436 | 152,017 |
| **Shareholder's equity and liabilities** | | |
| Total equity | 51,372 | 135,126 |
| Total liabilities | 12,064 | 16,891 |
| **Total equity and liabilities** | 63,436 | 152,017 |

- At the end of the period, cash plus short-term financial investments were NOK 50.5 million, compared to NOK 145.2 million as of 31 December 2022
- As a consequence of Lytix's cost-saving initiative, the cash runway has been prolonged through H1 2024

# Outlook

# Key objectives

- Clinical development
  - ATLAS-IT-05 study
    - Looking forward to report additional data from the patients still in the study
  - Verrica Pharmaceutical`s Phase II trial in BCC
    - Final results mid 2024
  - Neoadjuvant phase II study in earlier stage melanoma
    - Interim data H1 2025
    - Represents a greater commercial potential compared to a recurrent/metastatic setting.
  - Prepare LTX-401 for Clinical Phase
    - Global asset with a large commercial potential in several cancer diseases
- Business
  - Continue to capture value in the immuno-oncology space
    - Partnering
      - Explore additional commercial avenues trough industry research collaborations
      - Strategy is to out-license drug candidates with solid Phase II data
- Finance
  - The Company continues to explore strategic partnering opportunities as well as other ways to finance its development plans

# Q&A

IR enquiries:
gjest.breistein@lytixbiopharma.com

# Interim Financial Statements

# Condensed Interim statement of profit and loss

| *Amounts in NOK thousands* | *Unaudited* Q4 2023 | *Unaudited* Q4 2022 | *Unaudited* H2 2023 | *Unaudited* H2 2022 | *Unaudited* FY 2023 | FY 2022 |
|---|---|---|---|---|---|---|
| Revenue | - | - | 3,917 | 1,409 | 3,991 | 1,409 |
| Other operating income | 5,125 | 1,615 | 5,500 | 3,178 | 6,250 | 15,864 |
| **Total operating income** | 5,125 | 1,615 | 9,417 | 4,587 | 10,241 | 17,273 |
| Payroll and related expenses | (6,006) | (6,163) | (12,573) | (11,253) | (25,411) | (21,133) |
| Depreciation and amortization expenses | (17) | (13) | (34) | (24) | (62) | (30) |
| Direct R&D expenses | (15,329) | (14,847) | (28,281) | (28,194) | (68,323) | (50,974) |
| Other expenses | (3,377) | (4,430) | (6,776) | (6,897) | (13,323) | (10,832) |
| **Total operating expenses** | (24,729) | (25,453) | (47,665) | (46,368) | (107,118) | (82,968) |
| **Loss from operations** | (19,604) | (23,837) | (38,247) | (41,781) | (96,877) | (65,695) |
| **Net financial items** | 1,024 | (5,357) | 1,419 | 1,439 | 8,940 | 9,689 |
| **Loss before tax** | (18,580) | (29,195) | (36,828) | (40,343) | (87,937) | (56,006) |
| **Tax expense** | - | - | - | - | - | - |
| **Loss for the period** | (18,580) | (29,195) | (36,828) | (40,343) | (87,937) | (56,006) |

# Condensed Interim statement of financial position

| *Amounts in NOK thousands* | *Unaudited* 30.06.2023 | *Unaudited* 30.09.2023 | ***Unaudited*** **31.12.2023** | 31.12.2022 |
|---|---|---|---|---|
| **Assets** | | | | |
| **Non-current assets** | | | | |
| Property, plant and equipment | 144 | 127 | **110** | 124 |
| **Total non-current assets** | 144 | 127 | **110** | 124 |
| | | | | |
| **Current assets** | | | | |
| Trade and other receivables | 5,959 | 1,252 | **12,777** | 6,735 |
| Short-term financial investments | 41,961 | 32,609 | **23,183** | 50,606 |
| Cash and cash equivalents | 58,257 | 46,158 | **27,365** | 94,552 |
| **Total current assets** | 106,177 | 80,019 | **63,326** | 151,893 |
| **Total assets** | 106,321 | 80,147 | **63,436** | 152,017 |
| | | | | |
| **Shareholder's equity and liabilities** | | | | |
| **Issued capital and reserves** | | | | |
| Share capital | 4,007 | 4,007 | **4,007** | 4,007 |
| Share premium reserve | 82,115 | 64,945 | **47,365** | 131,119 |
| **Total equity** | 86,122 | 68,952 | **51,372** | 135,126 |
| | | | | |
| **Liabilities** | | | | |
| **Current liabilities** | | | | |
| Trade payables | 5,889 | 22 | **3,572** | 6,997 |
| Other current liabilities | 14,310 | 11,173 | **8,492** | 9,894 |
| **Total current liabilities** | 20,199 | 11,195 | **12,064** | 16,891 |
| | | | | |
| **Total liabilities** | 20,199 | 11,195 | **12,064** | 16,891 |
| | | | | |
| **Total equity and liabilities** | 106,321 | 80,147 | **63,436** | 152,017 |

# Condensed Interim statement of cash flows

| *Amounts in NOK thousands* | *Unaudited* Q4 2023 | *Unaudited* Q4 2022 | ***Unaudited*** **H2 2023** | *Unaudited* H2 2022 | ***Unaudited*** **FY 2023** | FY 2022 |
|---|---|---|---|---|---|---|
| **Cash flows from operating activities** | | | | | | |
| Loss for the period | **(18,580)** | (29,195) | **(36,828)** | (40,343) | **(87,937)** | 56,006) |
| **Adjustments for:** | | | | | | |
| Depreciation of property, plant and equipment | **17** | 13 | **34** | 24 | **62** | 30 |
| Share-based payment expense | **1,001** | 438 | **2,079** | 751 | **4,183** | 1,376 |
| Interest received | **(433)** | - | **(1,006)** | - | **(2,348)** | - |
| Increase/decrease in trade and other receivables | **(11,525)** | (1,079) | **(6,818)** | 908 | **(6,042)** | (1,055) |
| Increase/decrease in trade and other payables | **869** | 3,400 | **(8,135)** | 6,750 | **(4,828)** | 3,553 |
| **Cash generated from operations** | **(28,652)** | (26,422) | **(50,676)** | (31,909) | **(96,909)** | (52,102) |
| Income tax paid | **-** | - | **-** | - | **-** | - |
| **Net cash flows from operations** | **(28,652)** | (26,422) | **(50,676)** | (31,909) | **(96,909)** | 52,102) |
| **Investing activities** | | | | | | |
| Investments in tangible assets | **-** | - | **-** | (17) | **(49)** | (154) |
| Interest received | **438** | - | **1,007** | - | **2,351** | - |
| Increase/decrease in other investments | **9,425** | (697) | **18,778** | (50,606) | **27,423** | (50,606) |
| **Net cash from/(used in) investing activities** | **9,860** | (697) | **19,785** | (50,623) | **29,725** | (50,761) |
| **Financing activities** | | | | | | |
| Interest paid | **(1)** | - | **(1)** | - | **(3)** | - |
| Proceeds from share issue, not yet registered | **-** | - | **-** | - | **-** | 133 |
| **Net cash from/(used in) financing activities** | **(1)** | - | **(1)** | - | **(3)** | 133 |
| Net increase/(decrease) in cash and cash equivalents | **(18,793)** | (27,120) | **(30,892)** | (82,532) | **(67,187)** | (102,730) |
| Cash and cash equivalents at the beginning of the period | **46,158** | 121,671 | **58,257** | 177,084 | **94,552** | 197,282 |
| **Cash and cash equivalents at the end of the period** | **27,365** | 94,552 | **27,365** | 94,552 | **27,365** | 94,552 |